VILLA SISTEMI MEDICALI

# Visitor T15

MOBILE X-RAY SYSTEM

*Revision:* 2
*Version:* March 26, 2004
*File:* [M_30010E00R02.doc]

# User's Manual

**WARNING: The information that is printed within this manual is vital for the correct use of the equipment; please read it carefully before use.**

(This page is intentionally left blank)

# TABLE OF CONTENTS


1. SAFETY AND COMPLIANCE ..... 2
1.1. Electrical safety ..... 2
1.2. Mechanical safety ..... 2
1.3. Electromagnetic compatibility (EMC) ..... 3
1.4. Protection against ionizing radiation ..... 3
1.5. General disposal ..... 3
1.6. Application & final destination ..... 4
1.7. Interfaceability ..... 4
1.8. Classification ..... 4
1.9. Compliance ..... 5
1.10. Copyright ..... 5
2. COMPONENT IDENTIFICATION ..... 6
2.1. Overview ..... 6
2.2. Collimator ..... 6
2.3. Control panel ..... 7
2.4. Audible signals ..... 8
2.5. Signals and error messages ..... 9
3. MESSAGES ON THE DISPLAY ..... 10
4. FUNCTIONING ..... 12
4.1. Transport ..... 12
4.2. Positioning ..... 13
4.3. Collimator adjustment ..... 14
4.4. Start up and checks at the ignition ..... 15
4.5. Exposures ..... 16
*4.5.1. Operative procedure ..... 16*
*4.5.2. Programs for the Anatomical programming mode (APR MODE) ..... 17*
*4.5.3. Perform an exposure ..... 18*
*4.5.4. Useful information ..... 18*
*4.5.5. Optional: dosimeter (DAPmeter) ..... 19*
*4.5.6. Optional: Radiography with examination table and Potter Bucky grid ..... 20*
4.6. Shutdown procedure ..... 20
5. MAINTENANCE ..... 21
5.1. General Warnings ..... 21
5.2. Checks and inspection by the user ..... 21
5.3. Cleaning ..... 22
5.4. Disinfection ..... 22
6. TECHNICAL DATA ..... 23
6.1. Electrical data ..... 23
6.2. Functioning features ..... 23
6.3. Radiological data ..... 24
6.4. Environmental data ..... 25
6.5. Mechanical data ..... 25
*6.5.1. Unit sizes ..... 26*
6.6. Components specifications ..... 27
*6.6.1. Generator ..... 27*
*6.6.2. Tube-Housing Assembly ..... 28*
*6.6.3. Collimator ..... 30*
*6.6.4. DAP meter (dose-area product meter) (optional) ..... 30*
6.7. Accessories and options ..... 30
6.8. Compliance with Directives and Technical Standards ..... 30
6.9. Labels and symbols ..... 31
*6.9.1. Labels of the unit ..... 31*
*6.9.2. Internal symbols ..... 32*
*6.9.3. Various symbols ..... 32*
*6.9.4. Packing label ..... 32*
DOCUMENT STATUS ..... I

# 1. SAFETY AND COMPLIANCE

The purpose of this user's manual is to provide a set of easy to use instructions for the proper use of the system. All of the information contained herein is based on the current version of the system. Villa Sistemi Medicali reserves the right to improve and implement changes to the information herein to reflect any changes necessitated by technological enhancements to the system.

- This x-ray unit must be used in strict compliance with the safety instructions contained in this manual and must not be used for purposes other those for which it was intended
- The x-ray unit may only be operated by skilled, properly trained personnel with the required knowledge of x-ray safety practices and the proper use of x-ray equipment.

**The operator is responsible for the use of the system in compliance with the applicable standards concerning installation and use.**

- The unit must not be operated when electrical, mechanical, or radiological faults are present or when any of the indicators or alarm devices are malfunctioning.
- When used in conjunction with other apparatus, components, or modules, whose compatibility is uncertain, it is necessary to ensure the absence of any danger to the patient or operator. Consult Villa Sistemi Medicali for information.
- Villa Sistemi Medicali is responsible for the safety of its products only when maintenance, repairs, or modifications have been performed by Villa Sistemi Medicali or by personnel authorized by Villa Sistemi Medicali in writing.
- As with any technical apparatus, this x-ray unit must be used properly with periodic checks and maintenance as specified in the chapter "Programmed maintenance".
- The system safety circuits and devices must not, for any reason, be moved, modified, or omitted.

**Villa Sistemi Medicali cannot be held liable for any malfunction, damage, or danger resulting from improper use of the system or non-compliance with the rules for proper maintenance.**

## *1.1. Electrical safety*

- Only trained service personnel authorized by Villa Sistemi Medicali may remove the unit covers and only in accordance with the instructions contained in the Service Manual.
- This X-ray unit may only be used in environments or medical rooms in compliance with the applicable IEC standards.
- The X-ray unit must not be used in areas where there exists a danger of explosion.
- Cleaning and disinfecting agents, including those used on patients, may create an explosive, gaseous mixture. Use only those products in compliance with the applicable rules.

## *1.2. Mechanical safety*

- After positioning the unit, engage the parking brakes.
- Only use the proper handles to move the unit.
- Avoid collision with obstacles.

## 1.3. *Electromagnetic compatibility (EMC)*

This apparatus is in compliance with the applicable rule regarding EMC, Directive 89/336, that defines the max. allowed emission levels from electronic devices and the required immunity from interference caused by externally generated electromagnetic fields

It is not, however, possible to exclude radio signals coming from transmitters such as mobile phones or similar mobile radio devices. These and other transmitting devices, including those in compliance with the EMC standards, may influence the proper functioning of medical apparatus when used in proximity and with a relatively high transmitting power. Therefore, the use of radio equipment proximity to electronically controlled systems must be avoided in order to eliminate any interference risk.

Explanation:
*The electronic apparatus that meets the EMC standards has been designed so that, under normal conditions, any malfunctioning risk, caused by electromagnetic interferences, is avoided.*
*However, if radio signals coming from high frequency transmitters with a relatively high transmitting power are used near the electronic apparatus, the risk of electromagnetic incompatibility cannot be completely controlled.*

**Any transmissions by mobile radio equipment must be avoided.**
**Mobile phones must be switched off in zones close to the unit.**
**These rules must be applied when the unit is switched on (that is to say connected to the mains and ready for use).**

## 1.4. *Protection against ionizing radiation*

**Before any x-ray exposure, ensure that all the necessary protective precautions have been taken.**

During the use of x-rays, personnel present in the room must comply with the following rules concerning protection against ionizing radiation:

- When necessary, use protective shielding against radiation in addition to the shielding already provided on the unit.
- Use protective aprons containing a material equivalent to 0,35mm of lead. Material of this nature reduces radiation at 50kV by 99,95% and at 100kV by 94,5%.
- The best protection against radiation is distance. It is therefore recommended that you stay as far as possible from the x-ray source and the exposure target. For this purpose, use all of the cable length provided for the foot-switch.
- Avoid walking or standing directly in the x-ray beam.
- Always use the smallest possible field of exposure by closing properly the collimator diaphragms. The scatter dose produced depends principally on the volume of the irradiated object.

**Never modify or disconnect the safety circuits or devices designed to prevent accidental exposures.**

## 1.5. *General disposal*

Villa Sistemi Medicali produces radiological systems that are advanced in terms of safety and environmental protection. Assuming that the unit is properly used, there is no risk to people or the environment.
In order to comply with applicable safety requirements, it is necessary to use materials that may be harmful to the environment (for example: monobloc oil, protective lead, boards and electronic components). Therefore, where necessary, proper disposal methods, according to the regulations of the country where the unit is installed, should be followed.

**For this reason, the unit may not be disposed of along with industrial or domestic waste and must be regarded as hazardous waste.**

For additional information, contact Villa Sistemi Medicali.

## 1.6. *Application & final destination*

This unit is a portable x-ray system aimed to fulfil a wide range of clinical applications; it must be operated exclusively by qualified, trained personnel who have been informed of the risks linked to the use of ionizing radiation.

The compactness and maneuverability of the unit enables the operator to navigate through obstacles such as doors, small rooms, narrow aisles and lifts with ease and allows accurate positioning between patient beds. The ergonomic design of the unit allows the operator excellent visibility during operation and movement.

The perfectly balanced monobloc arm allows free movement and positioning even in the more awkward positions. The shape of the base allows easy positioning and handling under the patient beds. The position and shape of the four antistatic wheels make the system easy to move even on coarse surfaces.

**The system does not belong to the category of equipment designed for continuous operation.**

**The system is not used in direct contact with the patient; however, accidental contact of some unit parts with the patient and operator is possible.**

**Contact with the patient is non-invasive.**

**Contact with the operator is strictly for reasons linked to the use of the equipment (normal operation).**

The unit is suitable to be used for x-ray examinations and diagnosis dedicated to:

- Operating theater
- Sport medicine
- Plaster room
- First aid
- Pediatrics
- Orthopaedics

**This x-ray unit must not be used in areas where danger of explosion exists.**

## 1.7. *Interfaceability*

The device does not foresee any interaction with medicines; instead it's possible to apply to the unit the ionization chamber dosimeter as optional (mod. DIAMENTOR PX). It complies with the safety requirements foreseen by the 93/42/EEC Directive. However, the liability of the interface, if it has not been evaluated and authorized by Villa Sistemi Medicali in writing, is of the operator and/or the person who has performed the interface.

## 1.8. *Classification*

Protection against electrical hazards ..... Class I
Protection against direct and indirect contact..... Unit, Type B with Type B applied part
Protection against water penetration..... Common protection (IPXO)
Use condition protection ..... Continuous use with intermittent load

## 1.9. Compliance

This x-ray unit is in compliance with the electromedical devices Directive 93/42 EEC and with the other national and international standards in force.

The distributor (according to the European Directive 93/42/EEC) of the unit Visitor T15 is:

***Villa Sistemi Medicali***
Via delle Azalee, 3
20090 - Buccinasco - (MI) - Italia
Tel: +39-02-48.859.1
Fax: +39-02-48.81.844
E-mail: vsmservice@villasm.com

Information concerning the compliance can be required to Villa Sistemi Medicali.

The manufacturer (according to the European Directive 93/42/EEC) of the unit Visitor T15 is:

***Technix S.p.A.***
Via E. Fermi, 26
24050 Grassobbio, BG - ITALY
Tel: +39 035 33 56 78
Fax: +39 035 33 56 75

## 1.10. Copyright

The original release of this manual is in Italian language (file: AD30013I00RXX.doc). For further information, please refer to the Italian version.
The software contained in the unit belongs to Technix S.p.A. Upon receipt of the unit, the user acquires the right to use the software in combination with the unit. **This right is neither exclusive nor transferable.**
Written authorization to Technix S.p.A. is mandatory prior to any modifications for the unit use with functions other than the ones foreseen.

# 2. COMPONENT IDENTIFICATION

## 2.1. Overview

1. Monobloc
2. Goniometer
3. Monobloc handle
4. Collimator
5. Supply cable-winding
6. Equipotential node
7. Connector for Potter
8. X-ray handswitch
9. Foot brake
10. Cassette holder
11. Magneto-thermic switch
12. Supply cable
13. Handle for unit movement
14. Control panel
15. Arm safety lock for transport
16. Monobloc support arm
17. Safety lock for monobloc rotation

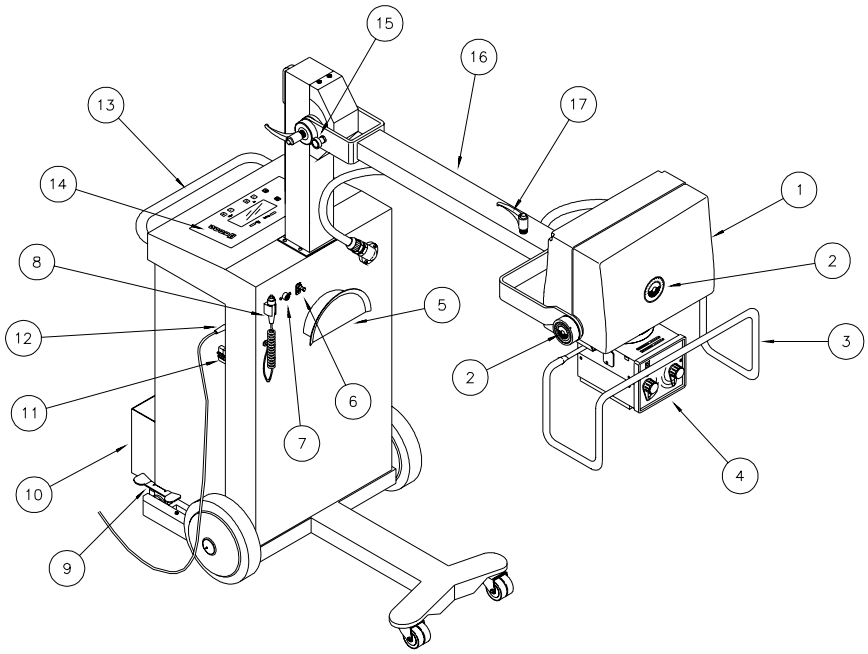



Figure 1

## 2.2. Collimator

1. Longitudinal collimation
2. Extensible meter for focus-skin distance check.
3. Transversal collimation
4. Lamp switching ON for the luminous irradiation field indication
5. Guides for the accessories positioning (filters or DAP dosimeter)

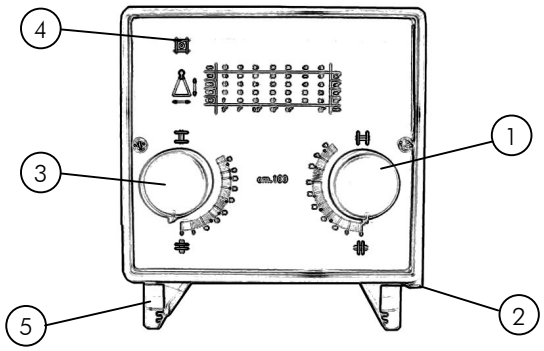



Figure 2

## 2.3. Control panel

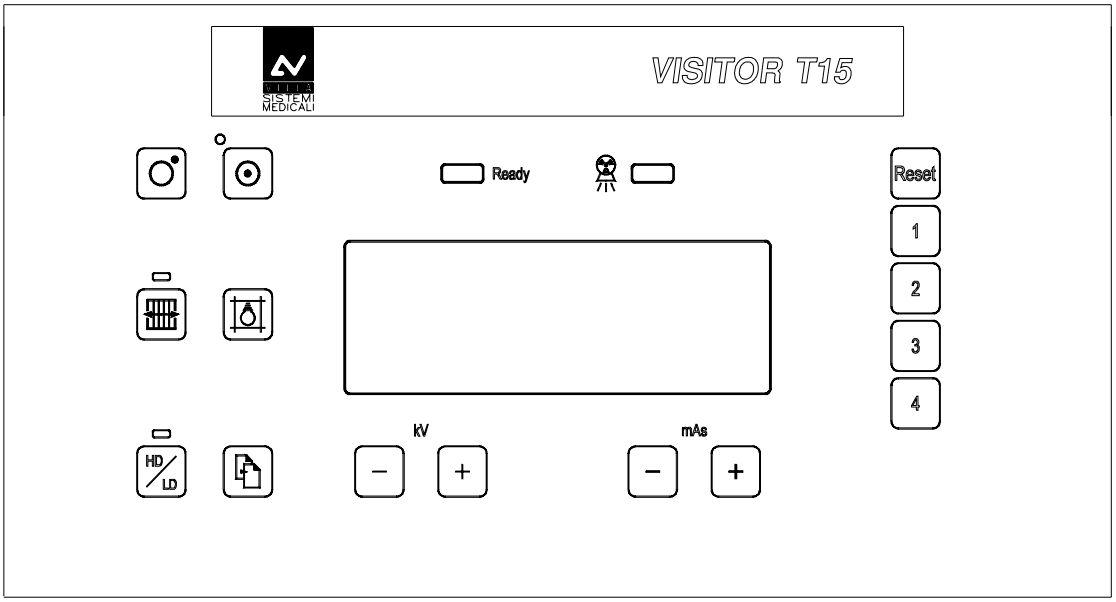
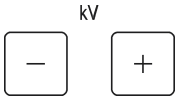
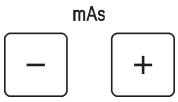
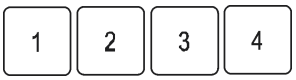



Figure 3

Here is a brief description of the keys function in standard use and the signals meaning.

| | | |
|---|---|---|
| | OFF | Unit OFF. |
| | ON | Unit ON, the green led indicates that the unit is connected to the mains and supplied. |
| | POTTER | External potter selection, only if the potter is inserted in the proper connector. |
| | COLLIMATOR | Collimator lamp ON.<br>(the lighting is timed for about 30s) |
| | POWER | HIGH or LOW POWER selection. The led ON indicates the HIGH POWER selection. |
| | MENU | Allows scrolling through pages in systems with more than one page. |

| | | |
|---|---|---|
|   | kV+ kV- | To modify KV value |
|   | mAs+ mAs- | To modify mAs value |
| | RESET | Return to the main menu. |
|   | F# | Function keys: F1, F2, F3, F4<br>They refer to the display line number (4 lines display). |
| | READY | ON when the unit is ready for radiography. |
| | X-RAY | When this led is ON there is x-ray emission |

## 2.4. *Audible signals*

Here is the list of the most important audible signals:

| | |
|---|---|
| 2 BEEPS | Storage ok |
| 3 BEEPS | Exposure ok |
| A LONG BEEP | Alarm, malfunction |

## 2.5. *Signals and error messages*

The unit foresees three types of alarm that can appear on the display:

- Warnings (WARN)
- Errors (ERR)
- Fatal Errors (FERR)

**Warnings (WARN)**
When this alarm appears, after taking the proper precautions, it is enough to press RESET on the control panel to go on to work with the same modes set. In order to interpret the alarm, refer to the tables indicated successively.

**Errors (ERR)**
When this alarm appears, after taking the proper precautions, it is enough to press RESET on the control panel to go on to work with the same modes set. In order to interpret the alarm, refer to the tables indicated successively. This type of alarm always leaves a trace, in fact the unit stores information about the error (date, time, kV and mAs) so that the service intervention is made easier.

**Fatal Error (FERR)**
This alarm does not allow operations to continue on the unit. It's necessary to switch the unit OFF. This type of alarm always leaves a trace, in fact the unit stores information about the error (date, time, kV and mAs) so that the service intervention is made easier.

**For the unit operator**

Every signal is displayed and appears in the language according to the unit configuration ("ITA", "ENG", "FRE", "GER", "SPA")

WARNING SIGNAL

| |
|---|
| ERR or WARN |
| MANUAL |
| |
| 63 4 |

The display shows error or warning messages on the first line, whilst the other lines show the unit status.
In this condition press "RESET" on the keyboard (see Figure 3) to go on to work with the same set modes.

FATAL ERROR SIGNAL

| |
|---|
| FATAL ERROR |
| |
| |
| |

The display shows the error message on the first line, whilst the other lines are blank.
In this condition it is necessary to turn the unit off, wait for some minutes, turn the unit on again and repeat the operations performed previously.
If the same error appears again, it is necessary to stop the unit use and call Service.

In order to interpret the unit messages, refer to the following pages.

# 3. MESSAGES ON THE DISPLAY

F = fatal error W = alarm S = unit status

| | Text | | Meaning | Action |
|---|---|---|---|---|
| S | READY | | The unit is ready to perform an exposure | |
| S | BUSY | | Preparation phase | Wait for "READY" message |
| S | MANUAL | | | |
| W | CLOCK OFF | | System clock error | Press RESET to proceed |
| F | POWER FAULT | | Charger or Chopper error<br>Energy not available | Turn off, wait for some minutes, turn on and if the error appears again, call Service |
| F | V3 FAULT | | Absence of V3 power supply | Turn off, wait for some minutes, turn on and if the error appears again, call Service |
| W | RESET APR | | APR checksum error | Press RESET to proceed |
| W | APR OUT OF RANGE | | An APR value is out of range | Set differently the parameters |
| W | TUBE SEASONING | | After a long idle period (3 months or more) it is necessary to proceed with the x-ray tube seasoning in order to avoid severe damages | Press RESET to proceed, call Service for the tube seasoning |
| F | FILAMENT | | Absence of filament current | Turn off, wait for some minutes, turn on and if the error appears again, call Service |
| W | HOT TUBE | | The monobloc temperature has achieved the max. allowed value | Wait for the monobloc cooling |
| F | V2 FAULT | | Absence of V2 power supply in the set mA and kV circuit | Turn off, wait for some minutes, turn on and if the error appears again, call Service |
| F | STARTER INTERLOCK | | Error during the start time | Press RESET to proceed and repeat exposure |
| F | CHOPPER FAULT | | Chopper error | Press RESET to proceed, repeat x-rays |
| W | TIME OUT | | The x-ray handswitch has been pressed at the 1st step for more than 15 secs. | Release the handswitch and repeat radiography |
| F | LACK OF X-RAY | | kV don't reach the 75% of the set value within the first 10ms of exposure or lack of x-rays. | Press RESET to proceed and repeat exposure |
| F | MAX TIME | | The max. exposure time has been achieved (2s) | Press RESET to proceed and repeat exposure |
| F | DATA ERR. | | Memory error, data checksum error | Turn off, wait for some minutes, turn on and if the error appears again, call Service |
| W | MAN STOP RX | | The x-ray handswitch has been released before the end of exposure | Press RESET to proceed |
| F | INVERTER KV ERROR | | During x-ray emission kV decrease under 75% or increase over 110% of the set value or the H.V. circuit has unbalanced during exposure | Press RESET and repeat exposure |
| F | INVERTER OVERLOAD | | Inverter power out of range | Press RESET and proceed |
| F | INVERTER FAULT | | IGBT drivers error | Press RESET and proceed |
| F | ERR. TUBE CALIB. | | X-ray tube calibration error | Call Service |
| F | HAND SWITCH ERR | | Faulty x-ray handswitch | Check the x-ray handswitch integrity, turn off and on again the unit, then try again. If the error appears again, call Service |
| W | Dosimeter | DAP INACTIVE | The dosimeter is not connected | - |
| - | | MAX DOSE | The doses meter has reached the max.value that can be displayed | Press F1+RESET to reset the value |
| S | | DAP READY | The dosimeter is ready | - |
| W | | DAP ERROR | The dosimeter is connected, but in fault | Press RESET and call Service |
| - | | DAP RESET | The sum of the product-area doses have been reset | - |

The table below shows all the messages and signals in the five languages that can be set.

| English (GB) | Italian (I) | French (F) | German (D) | Spanish (ES) |
|---|---|---|---|---|
| ENG | ITA | FRE | GER | SPA |
| CLOCK OFF | ERR.OROLOGIO | CHRONO DEF. | TAKTGEBER DEFEKT | FALLO RELOJ |
| POWER FAULT | POTENZA GUASTA | BAT.DEFECT. | STROMVERSORG. DEF | FALLO ACUMUL. |
| V3 FAULT | ERRORE V3 | V3 DEFECT. | V3 DEFEKT | FALLO V3 |
| RESET APR | INI.APR | INI.APR | APR-DATEN DEFEKT | INI.APR |
| APR OUT OF RANGE | ERRORE IN APR | APR DEFECT. | APR-WERT FALSCH | FALLO APR |
| TUBE SEASONING | FORM.DEL TUBO | FORM. DU TUBE | RÖHRE ENFAHREN | AJUSTE DEL TUBO |
| FILAMENT | FILAMENTO | FILAMENT | HEIZKREIS-FEHLER | FILAMENTO |
| HOT TUBE | TUBO CALDO | TUBE CHAUD | RÖHRE HEISS | TEMPER. |
| V2 FAULT | ERRORE V2 | V2 DEFECT. | V2 DEFEKT | FALLO V2 |
| STARTER INTERLOOK | STARTER BLOCCATO | BLOCAGE DEMARREUR | ANLAUF-FEHLER | BLOQUEO CEBADOR |
| CHOPPER FAULT | CHOPPER GUASTO | HACHEUR DEFECT. | CHOPPER-FEHLER | FALLO PULSADOR |
| TIME OUT | TEMPO SCADUTO | TEMPS EXPIRE | PREP ZU LANG | FUERA TIEMPO |
| READY | PRONTO | PRET | BEREIT | LISTO |
| BUSY | ATTESA | ATTENDRE | WARTEN | ESPERA |
| LACK OF X-RAY | ERRORE RAGGI | FAUTE RAYON | KEINE STRAHLUNG | SIN RADIACION |
| MAX TIME | TEMPO MAX | TEMPS MAX | MAX EXP ERREICHT | TIEMPO MAX |
| DATA ERR. | ERR. DATI | FAULE DE VALEUR | DATEN-FEHLER | FALLO DATO |
| MAN STOP RX | STOP MANUALE | STOP MANUAL | EXP UNDERBROCHEN | INTERRUP. MANUAL |
| INVERTER KV ERR. | ERR.KV INVERTER | TRANSF.KV DEFECT | WANDLER KV FEHLER | FALLO KV TRANSF |
| INVERTER OVERLOAD | SOVRACCARICO INV. | TRANSF.SURCHARGE | WANDLER ÜBERLAST | SOBRECARGA TRANSF |
| INVERTER FAULT | ERRORE INVERTER | TRANSF.DEFECTUEUSE | WANDLER FEHLER | FALLO TRANSF |
| ERR.TUBE CALIBR. | ERR. CALIB.TUBO | CALIB.DEFECT. | RÖHRE KALIBRIEREN | FALLO CALIB. |
| MANUAL | MANUALE | MANUAL | MANUELL | MANUAL |
| HAND SWITCH ERR | ERR.PULSANTE RX | BOUTON DEFECT. | HANDSCHALT.DEF | FALLO MANDO |
| INACTIV | INATTIV | INACTIF | INAKTIV | INACTIV |
| ACTIV | ATTIVO | ACTIF | AKTIV | ACTIV |
| NOT OK | NON OK | NON OK | NOT OK | NO OK |
| MAXDOSE | MAXDOSE | MAXDOSE | MAXDOSE | MAXDOSE |

# 4. FUNCTIONING

## 4.1. *Transport*

For the transport of the unit, consider the following instructions:

- The unit must be OFF, the supply plug must be removed from the socket outlet and the cable wound. (See Par. 4.6 "Shutdown procedure").
- Place the monobloc - collimator group vertically and activate its rotation safety lock (see Figure 4).
- Pull the safety knob and rotate it till it is taken out (see Figure 5).
- Move downwards the arm by using the handles and by keeping in vertical position the monobloc-collimator group; when the parking position is reached (see Figure 6) rotate and engage the safety lock.
- Release the parking brake (see Figure 7 and Figure 8)
- Move the unit by using only the proper handles for the transport.
- Don't move the unit on surfaces with inclination higher than 10°.
- In order to overtake obstacles, it is possible to use the handle placed on the column.

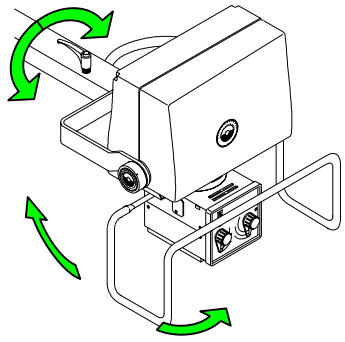


Figure 4
Movements of the monobloc - collimator group

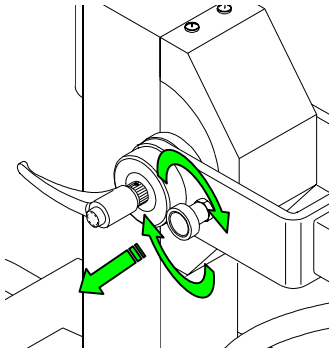


Figure 5
Safety knob

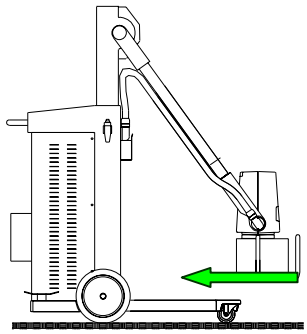


Figure 6
Parking position

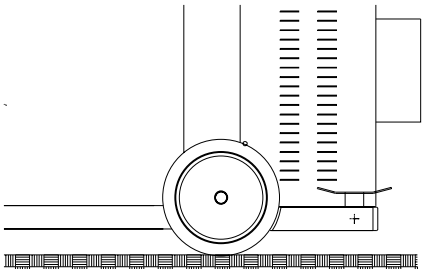


Figure 7
pos.1: deactivated brake

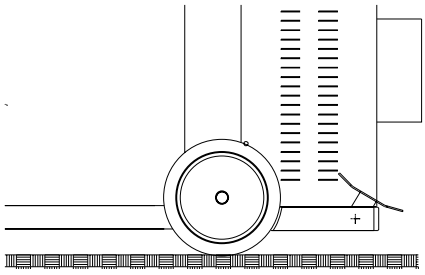


Figure 8
pos.2: activated brake

## 4.2. Positioning

For positioning the unit the following instructions should be considered:

**Don't move the unit when the brakes are activated. For the movements use the proper handles.**

- Pull the safety knob and turn it till it is taken out (see Figure 5).
- For adjusting and positioning the arm height use the handle on the monobloc. (see Figure 8).
- Position the monobloc-collimator assembly over the relevant area of the patient (see Figure 10 - Figure 11).
- Turn the unit ON (see the paragraph "4.4 "Start up and checks at the ignition")
- Turn the collimator lamp ON (the lamp will stay on for about 30secs).
- Collimate the x-ray beam to the dimension of the cassette (see the next paragraph)
- If necessary, release the brake to perform this operation (don't forget to set it again!).
- When the positioning has been completed, lock all the movements braking handles and the parking brake.

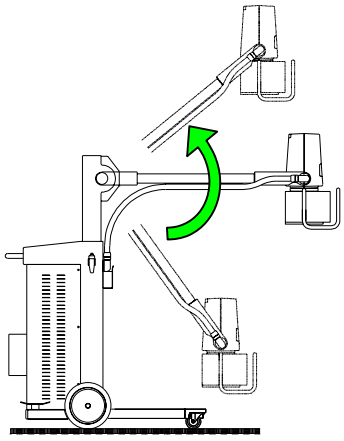


Figure 9

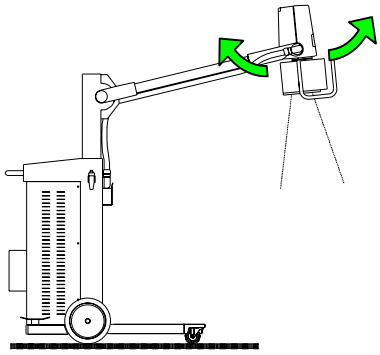


Figure 10

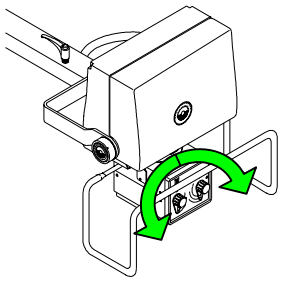


Figure 11

## *4.3. Collimator adjustment*

1. On the frontal panel of the collimator, there are two knobs for the beam adjustment (width and length) as well as the push-button to turn ON the collimator lamp (see Figure 12). It is possible to turn the lamp ON by pressing the COLLIMATOR push-button placed on the control panel.

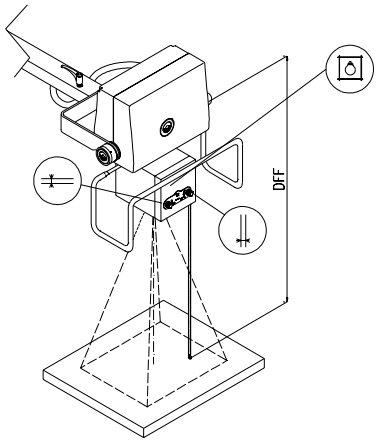



Figure 12

The extensible meter allows to measure with accuracy the focus-film distance (FFD).

2. If necessary, rotate the collimator (see Figure 13).

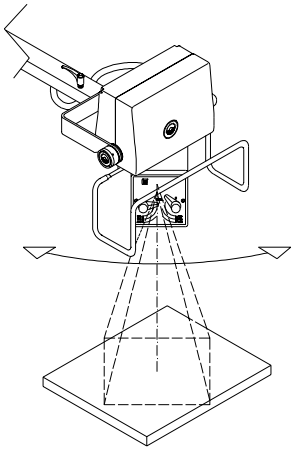
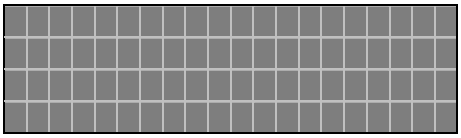


Figure 13

## *4.4. Start up and checks at the ignition*

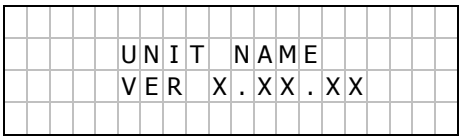
1. Connect the unit to the mains. Voltage presence is indicated by the lightening ON of the yellow led placed aside the ON button. If, while it is plugged, the red light is off, check that the automatic switch lever, placed aside the unit, is up (ON position)
2. Turn the unit ON, pressing the ON button, follow step by step the Start up phase and verify its performance by the following comparison:

    - check of the display: every digit is completely ON (every pixel is dark);

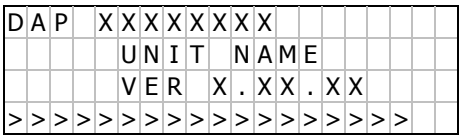


    - check of leds and beepers: all the leds of the keyboard turn ON and the beeper emits a prolonged sound;
    - software version:

without dosimeter




with dosimeter



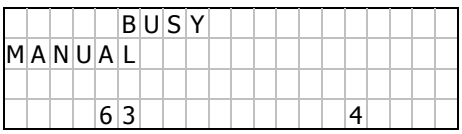

XXXXXXXX can have the following values:

READY: the reading of the chamber is enabled and it works properly
ERROR: the reading of the chamber is enabled but it does not work properly, it is not present or it is not connected.
INACTIVE: status displayed after ERROR signal and after pressing the key RESET.

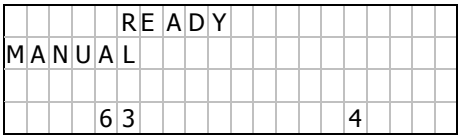
If the DAP is accepted to the test, the writing READY appears and the system goes on.
If it is not accepted, the writing ERROR appears and the audible error alarm is activated.
At this point it is necessary that the operator intervenes; by pressing the key RESET it is possible to go on with the start up of the unit by indicating DAP INACTIVE.

    - phase of capacitors battery charge:

<u>*Start Up:*</u> on the unit it is possible to set the radiological data, including the APR, but it is not possible to perform an exposure till the writing "READY" appears on the display




1. When the Start up is finished, the writing "READY" will appear on the display, the unit is ready for use.

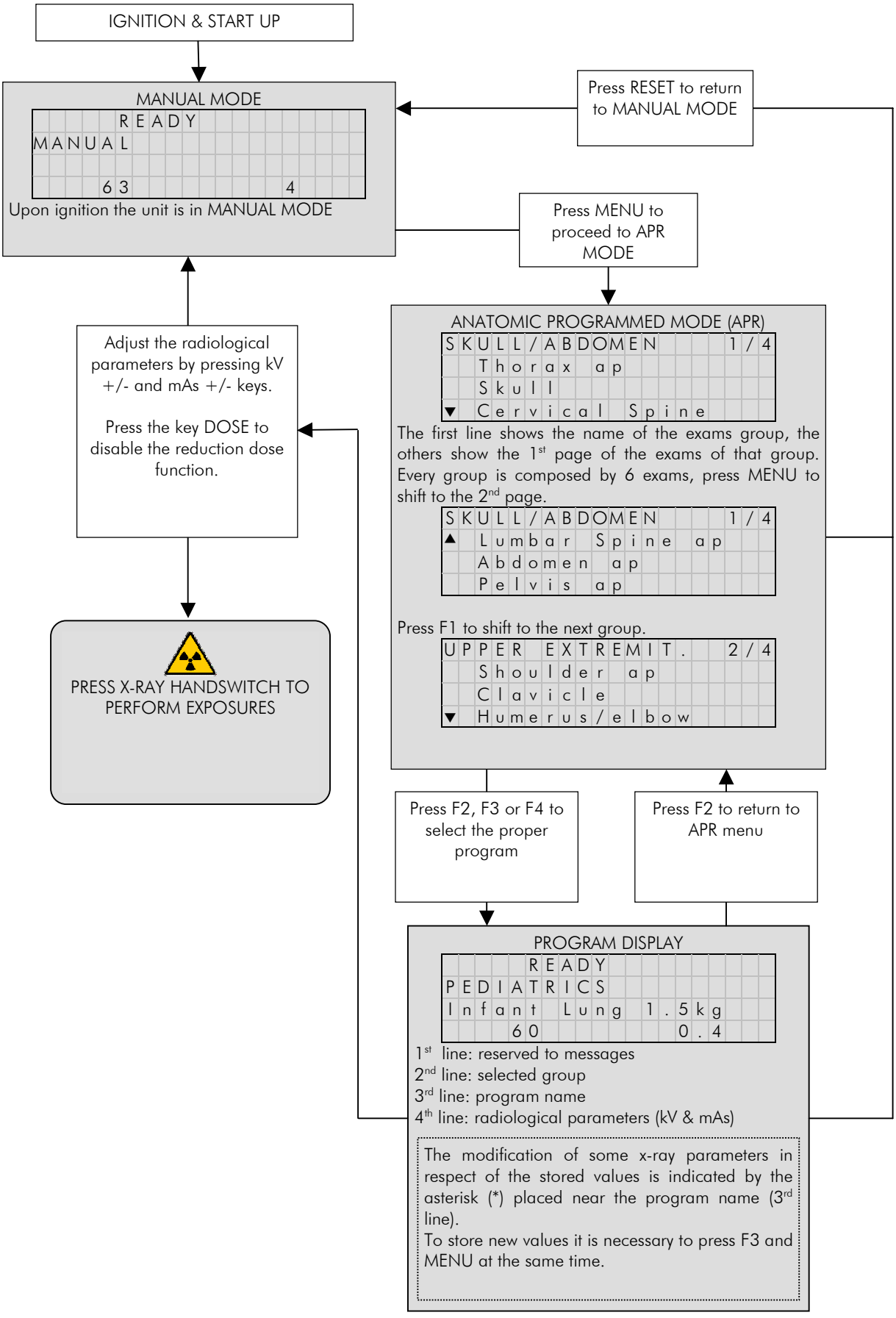



If it does not occur, it is probable that the unit is faulty or that there are some malfunctions, contact the authorized service personnel.

## 4.5. *Exposures*

### 4.5.1. Operative procedure

Set the exposure data by following the operative procedure here below.


IGNITION & START UP
MANUAL MODE
READY
MANUAL
63 4
Upon ignition the unit is in MANUAL MODE
Press RESET to return to MANUAL MODE
Press MENU to proceed to APR MODE
ANATOMIC PROGRAMMED MODE (APR)
SKULL/ABDOMEN 1/4
Thorax ap
Skull
Cervical Spine
The first line shows the name of the exams group, the others show the 1st page of the exams of that group. Every group is composed by 6 exams, press MENU to shift to the 2nd page.
SKULL/ABDOMEN 1/4
Lumbar Spine ap
Abdomen ap
Pelvis ap
Press F1 to shift to the next group.
UPPER EXTREMIT. 2/4
Shoulder ap
Clavicle
Humerus/elbow
Adjust the radiological parameters by pressing kV +/- and mAs +/- keys.
Press the key DOSE to disable the reduction dose function.
PRESS X-RAY HANDSWITCH TO PERFORM EXPOSURES
Press F2, F3 or F4 to select the proper program
Press F2 to return to APR menu
PROGRAM DISPLAY
READY
PEDIATRICS
Infant Lung 1.5kg
60 0.4
1st line: reserved to messages
2nd line: selected group
3rd line: program name
4th line: radiological parameters (kV & mAs)
The modification of some x-ray parameters in respect of the stored values is indicated by the asterisk (*) placed near the program name (3rd line).
To store new values it is necessary to press F3 and MENU at the same time.

### 4.5.2. Programs for the Anatomical programming mode (APR MODE)

Here is a table with the APR default values. Consider that they are valid by placing the x-ray tube with a SID (Source-Image receptor Distance) of 100 cm without grid.
In case of cassettes with grid it is necessary to increase the mAs values by four increments.

| Folder | Part of Body | kV | mAs | SC [DIN][1] |
|---|---|---|---|---|
| **1/4 SKULL / ABDOMEN** | Thorax ap | 85 | 3.2 | 200 |
| | Skull | 78 | 5.0 | 400 |
| | Cervical Spine | 66 | 6.3 | 400 |
| | Lumbar Spine ap | 78 | 6.3 | 400 |
| | Abdomen ap | 85 | 5.0 | 400 |
| | Pelvis ap | 77 | 3.2 | 400 |
| **2/4 UPPER EXTREMITIES** | Shoulder ap | 66 | 16.0 | 200 |
| | Clavicle | 66 | 10.0 | 200 |
| | Humerus/elbow | 60 | 4.0 | 200 |
| | Forearm | 52 | 3.2 | 200 |
| | Wrist | 48 | 2.5 | 200 |
| | Hand ap | 46 | 2.5 | 200 |

| Cartella | Part of Body | kV | mAs | SC [DIN][1] |
|---|---|---|---|---|
| **3/4 LOWER EXTREMITIES** | Hip/Femur | 74 | 5.0 | 400 |
| | Knee | 66 | 4.0 | 200 |
| | Lower Leg | 60 | 4.0 | 200 |
| | Ankle | 55 | 4.0 | 200 |
| | Calcaneus | 52 | 3.2 | 200 |
| | Foot | 48 | 2.0 | 200 |
| **4/4 CHILDREN** *Added Filter 1mmAl + 0,2mmCu* [2] | Thorax 1.0 Kg | 60 | 0.2 | 400 |
| | Thorax 2.0 Kg | 62 | 0.4 | 400 |
| | Thorax 4.0 Kg | 72 | 0.4 | 400 |
| | Thorax 6.0 Kg | 74 | 0.4 | 400 |
| | Thorax 8.0 Kg | 76 | 0.4 | 400 |
| | Thorax 10 Kg | 76 | 0.63 | 400 |

Here is the list of the APR programs and groups names in the five settable languages.

| APR Groups and programs | | | | |
|---|---|---|---|---|
| English (GB) | Italian (I) | French (F) | German (D) | Spanish (ES) |
| SKULL/ABDOMEN | CRANIO/ADDOME | CRANE/ABDOMEN | SCHÄDEL/ABDOMEN | CRANEO/ABDOMEN |
| Thorax ap | Torace ap | Thorax ap | Thorax ap | Thorax ap |
| Skull | Cranio | Crane | Schädel | Craneo |
| Cervical Spine | Spina Dorsale | Col.Cervical | HWS | Vertebras Cerv. |
| Lumbar Spine ap | Spina Lombare | Col.Lumbaire | LWS ap | Vertebras Lumb. |
| Abdomen ap | Addome ap | Abdomen ap | Abdomen ap | Abdomen ap |
| Pelvis ap | Bacino ap | Bassin ap | Becken ap | Pelvis ap |
| UPPER EXTREMIT. | ESTREMITÁ SUP. | EXTREMITES SUP. | OBERE EXTREMIT. | EXTREM. SUPERIOR |
| Shoulder ap | Spalla ap | Epaule ap | Schulter ap | Hombro |
| Clavicle | Clavicola | Clavicule | Schluesselbein | Clavicula |
| Humerus/elbow | Omero/Gomito | Humerus/Coude | OA/Ellenbogen | Humero/Codo |
| Forearm | Avambraccio | Bras inf. | Unterarn | Antebrazo |
| Wrist | Polso | Poignet | Handgelenk | Muneca |
| Hand ap | Mano ap | Main ap | Hand ap | Mano ap |
| LOWER EXTREMIT. | ESTREMITÁ INF. | EXTREMITES INF. | UNTERE EXTREMIT. | EXTREM. INFERIOR |
| Hip/Femur | Fianco/Femore | Hanche/Femur | Huefte/OS | Coxal/Femur |
| Knee | Ginocchio | Genou | Knie | Rodilla |
| Lower Leg | Gamba inf. | Jamb inf. | US | Pierna inf. |
| Ankle | Anca | Art.Tibio Tors. | Fussgelenk | Tobillo |
| Calcaneus | Calcagno | Calcaneum | Fersenbein | Calcaneus |
| Foot | Piede | Pied | Fuss | Pie |
| CHILDREN | BAMBINI | ENFANTS | KINDER | NINOS |
| Thorax 1.0 Kg | Torace 1.0 Kg | Thorax 1.0 Kg | Thorax 1.0 Kg | Thorax 1.0 Kg |
| Thorax 2.0 Kg | Torace 2.0 Kg | Thorax 2.0 Kg | Thorax 2.0 Kg | Thorax 2.0 Kg |
| Thorax 4.0 Kg | Torace 4.0 Kg | Thorax 4.0 Kg | Thorax 4.0 Kg | Thorax 4.0 Kg |
| Thorax 6.0 Kg | Torace 6.0 Kg | Thorax 6.0 Kg | Thorax 6.0 Kg | Thorax 6.0 Kg |
| Thorax 8.0 Kg | Torace 8.0 Kg | Thorax 8.0 Kg | Thorax 8.0 Kg | Thorax 8.0 Kg |
| Thorax 10 Kg | Torace 10 Kg | Thorax 10 Kg | Thorax 10 Kg | Thorax 10 Kg |

[1] SC is the sensitivity class. According to DIN 6867-10, a class 400 film/screen system (SC = 400) can cover a sensitivity range of Smin = 320 DIN to Smax = 560 DIN. From the derived dose value Ks the tolerance for S will be approx. ± 30%.

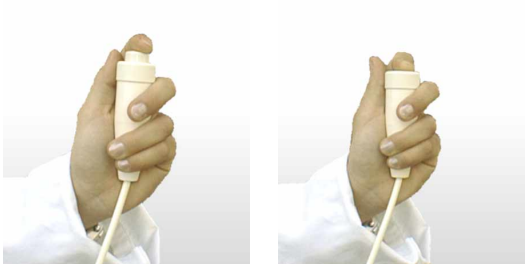
[2] The filter combination of 1 mmAl + 0,1 mmCu is also permissible

### 4.5.3. Perform an exposure

**Before performing an exposure, make sure that all the necessary precautions against radiation have been taken.**

**After a long idle period (3 months or more) it is very important to proceed with the X-RAY TUBE SEASONING. It is necessary to avoid high voltage discharges that could be destructive for the X-ray tube. The seasoning procedure is described in the Service Manual.**

- Keep away as much as possible from the x-ray source
- If on the display "READY" appears and the READY led is ON, the exposure can be controlled.
- The emission control is made up of a two-steps switch.
  1°step: preparation (about 1 s)
  2°step: exposure control
- It is possible to press the exposure control at once (second step). Then there is a delay of about 1.2 s before the real exposure.
- Hold the x-ray control down till the exposure has been performed properly (3 beeps).



1° step "prep" 2° step "rad"

Figure 14

The x-ray handswitch activates both the x-ray preparation phase "prep" and the emission phase "rad". The Figure 14 shows how to operate the handswitch to activate the preparation and the emission phases. It is not possible to activate the emission phase "rad" without preparation; however, it is possible to perform preparation without activating the emission.

The most frequent alarms during the use of the x-ray handswitch are the following:

1. TIME OUT – The x-ray handswitch has been pressed at the "1st step" (preparation) for more than 15s. In order to perform radiography, it is necessary to release the handswitch and repeat the procedure.
2. MAN STOP RX – The x-ray handswitch has been released before the end of exposure. In this case, the display will show the radiological data obtained. In order to repeat the exposure, it is necessary to press RESET.

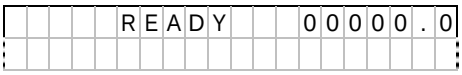
### 4.5.4. Useful information

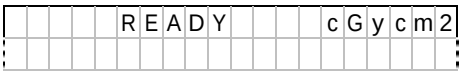
- Only if the display shows the writing "READY" and the READY led is ON, it is possible to perform an exposure.
- The 1st line of the display shows the use messages and the error signals.
- The 4th line of the display shows the radiological parameters.
- After every exposure, the 4th line shows the radiological parameters and, in the middle, the exposure time.
- While shifting from APR MODE (Anatomical programming) to the MANUAL MODE, radiological parameters do not change.

### 4.5.5. Optional: dosimeter (DAPmeter)

The unit can be supplied, on request, with a ionizing chamber dosimeter (dose-area product meter, DAP meter) installed. The DAPmeter function is to measure the dose-area product [cGgcm$^2$] in output towards the patient.
The device that can be installed is type PTW-Freiburg DIAMENTOR PX - T11020-00011.
Only authorized service personnel can perform the installation and the maintenance of the dosimeter.

If DAPmeter has been installed and it works properly, the first line of the display shows alternatively the *measures summation* and the measurement unit [cGycm$^2$]:




The *measures summation* is the sum of all the dose-area products read by the chamber. By pressing F1+RESET, the value resets.

$$\sum_{i=1}^{n} \text{dose}_i \cdot \text{area}_i$$

"n" is the number of exposures performed after the last time that F1+RESET has been pressed.

In order to determine the correct Dose Area Product to which the patient has been exposed, it is necessary to press F1+RESET before performing any exposures.
The possible measuring range is included between 00000.0cGycm$^2$ and 99999.9cGycm$^2$. When the measures summation exceeds 99999.9cGycm$^2$, the message "MAXDOSE" will appear. The presence of this message does not exclude the possibility to perform exposures.

### 4.5.6. Optional: Radiography with examination table and Potter Bucky grid

**The examination table or the Potter Bucky that can be connected to the unit must be according to the Medical Devices Directive EEC 93/42.**

After positioning the cassette and the patient, follow these instructions:

1. connect the Potter Bucky grid or the table for the examination to the socket outlet placed on the frontal unit part;
2. press the push-button for the Potter Bucky selection, if the potter works properly the led of the key turns on;
3. place monobloc and collimator, set the exposure field as shown previously;
4. lock the parking brake;
5. select manually the values of kV and mAs or in APR mode, by choosing the data about the examination that you need to perform;
6. pick up the x-ray handswitch;
7. keep away at least 2m from the x-ray tube;
8. press and hold down the handswitch in "prep" position for the preparation (about 1.2s);
9. press the x-ray handswitch in "rad" position;
10. hold down the x-ray handswitch till the exposure time is finished. The end of the exposure is indicated by three Beeps emitted by the audible signal of the unit.

Note: occasionally when the potter grid has been selected “non consent to proceed” may appear, in this case check the connection.

Note: it is possible to press the x-ray handswitch fully ("rad" position) from the beginning. In this case the x-ray exposure will be performed automatically after the preparation.

## 4.6. *Shutdown procedure*

**Ensure unit is switched off before removing the connector from the mains outlet**

When finished the examination, do the following:

1. Turn the unit off by acting on the dedicated button OFF placed on the control console.
2. Disconnect the cable and wrap it on the wire-wrap.
3. Place the unit in parking position (lowered, with activated mechanical brakes).

# 5. MAINTENANCE

Villa Sistemi Medicali can supply, on request, a programmed maintenance plan to be performed on the unit.

## 5.1. General Warnings

As with any medical device, this system requires:

- proper use;
- regular checks by the user;
- maintenance and repairs by the authorized personnel.

Operational reliability of the unit is kept by following these precautions.

Villa Sistemi Medicali can provide, on request, circuit drawings, parts list, adjustment instructions or further information for the unit repair.

**As users of x-ray units it is necessary to take these precautions in compliance with the prevention standards formulated by the laws concerning the medical equipment.**

The unit needs regular checks and maintenances. The purpose of the following warnings is to keep a good operating and safety level.
The unit includes mechanical parts that are subjected to wear during normal use of the equipment. After a long period of use, it is possible that the safety of the system may decrease due to the parts wear.
Regular checks and maintenance are necessary to protect the patient and the operator from damage as a result of the breakage of any mechanical parts..
The correct adjustment of the electro-mechanical and electronic modules is essential, as this has a direct influence on the unit operation, the image quality, the electrical safety and the exposure level of radiation to which the medical personnel and patients are subjected
The maintenance plan includes checks and prevention measures to be done by expressly authorized personnel and at the unit owner's charge.

**In the replacement of any parts that can affect the units safe operation, use only original spare parts.**

## 5.2. Checks and inspection by the user

The user must check the x-ray unit as indicated in the table below. In the event of operational faults or other deviations in respect of the standard operative behaviour, the user must turn off the unit. The unit may only be operated after repairs have been made.

**If a faulty or malfunctioning unit is used, risks to the operators and patients can increase.**

| Summary of the periodical checks | |
|---|---|
| Daily: | Check the functionality of alarms, displays and indicators.<br>Check the warning and danger labels integrity. |
| Weekly: | Check for oil leakage from the monobloc.<br>Check unusual noises in the monobloc during x-ray emission<br>Check the x-ray tube and collimator centering |
| Every 6 months: | Check the brakes and the directional handle functionality. |
| Yearly: | Contact the technical after-sale service to perform the constancy and reproducibility tests, as indicated by IEC 1223-2 and IEC 1223-11 standards, as well as the other operating tests of the unit, as instructed in the programmed maintenance plan. (see Service Manual). |

## 5.3. *Cleaning*

Please take the following information into consideration before choosing a detergent:

- To clean plastic surfaces, simply use water and soap, and nothing else. If other detergents are used (e.g. with a high alcoholic content, or corrosive solvents, or abrasive detergents), the material will tend to break or opacify.
- To clean enameled parts and aluminium surfaces, simply rub them with a wet cloth and a delicate detergent, after that rub them with a dry wool cloth.
- As regards, chromium-plated surfaces, only rub them using dry wool clothes; do not use any detergent.
- To clean the other surfaces of the equipment, never use highly alcoholic products, corrosive or abrasive detergents and solvents

**Before cleaning the unit, please take the following actions:**

- **Turn off the unit and unplug the mains power supply cable.**
- **Ensure that no liquid seeps into the unit, so as to avoid short-circuiting or corroding the electrical and electromechanical parts**.

## 5.4. *Disinfection*

To disinfect the equipment it's advisable to use a common liquid solution featuring an aldehyde base or disinfectants featuring an ampholytic surface-active agent base (e.g. Tego 103, Korsolin).
Substitute disinfectants releasing chlorine or based on phenols are likely to weaken the materials, hence they are much to be avoided. The same limitations apply to undiluted solutions featuring a high alcoholic content.
Do not use disinfectant spray; it might penetrate the system, and its safety would not be guaranteed any longer (damages possibly affecting electrical and electromechanical parts, formation of flammable air mixtures and vapor solutions).

**In cases where there is a danger that disinfection products may form inflammable or explosive gaseous mixtures, always ensure that such gases have dispersed before re-using the equipment.**

# 6. TECHNICAL DATA

## 6.1. Electrical data

| Description | Data | | |
|---|---|---|---|
| *Voltage* | 115/230Vac ±10% standard monophase with automatic unit prearrangement in function of the mains (plug & play). | | |
| *Frequency* | 50/60Hz standard | | |
| *Absorbed current* | Values of current absorbed by the unit in the different operative conditions and in the two power supply values: | | |
| | *Operative condition* | *115 Vac / 50Hz* | *230 Vac / 50Hz* |
| | Charger On | 5,5 $A_{MAX}$ | 3,4$A_{MAX}$ |
| | Stand By | 0,87A | 0,58A |
| | Stand By + Collimator Lamp | 2,3A | 1,5A |
| | Stand By + Charger On | 5,1A | 3,0A |
| | Stand By + Collimator Lamp + Charger On | 6,7A | 3,8A |
| | Preparation | 4,3A | 5,5A |
| | Preparation + Collimator Lamp | 5,5A | 7,3A |
| | X-ray emission + Collimator Lamp | 3$A_{PK}$ | 3$A_{PK}$ |
| *Line compensation* | Automatic | | |
| *Line resistance* | <1Ω @115/230Vac | | |
| *Standard socket outlet* | 16A @230Vac | | |
| *Isolation class* | Class I with applied parts type B | | |
| *Use conditions* | Continuous functioning with intermitting load | | |
| The unit is not suitable to the use where danger of inflammable mixtures with air or nitrous oxide exists. | | | |

## 6.2. Functioning features

| Description | Data |
|---|---|
| *User's interface* | Keyboard with LCD alphanumeric display, 4 lines X 20 characters for all the operative parameters and messages of possible faulty status.<br>Service program for faults finding.<br>Microprocessor management. |
| *Settable languages* | Italian, English, French, German, Spanish, through configuration program |
| *Radiography control* | By handswitch with extendible cable. It is proposed the use of the last kV value used in manual mode or APR.<br>Upon the ignition, the unit is in manual mode with default values. |
| *Safeties* | Filament current<br>Monobloc temperature<br>Overload<br>Max kV or H.V. fault<br>Stored data check<br>Microcontroller auto test |

## 6.3. *Radiological data*

<table>
<tr><th>Characteristic</th><th colspan="5">Performances</th></tr>
<tr><td>Working technique</td><td colspan="5">2 points technique with kV and mAs setting</td></tr>
<tr><td>APR anatomic program</td><td colspan="5">24 exams memorization (4 programs each of 6 exams) available in the 5 different selectable languages.</td></tr>
<tr><td>Exposure control</td><td colspan="5">Constant kV and mA during the whole exposure</td></tr>
<tr><td>Power reduction</td><td colspan="5">It can be selected of L.P. (50%) or H.P. (100%)</td></tr>
<tr><td>Generator power in DC current</td><td colspan="5">15kW @100kV</td></tr>
<tr><td>Inverter frequency</td><td colspan="5">20kHz</td></tr>
<tr><td>Max. inverter frquency in high voltage</td><td colspan="5">40kHz</td></tr>
<tr><td>Max.ripple</td><td colspan="5"><2% @100kV</td></tr>
<tr><td>Rise time</td><td colspan="5"><2ms @100kV</td></tr>
<tr><td>mA variation range @115/230Vac</td><td colspan="5">40 ÷ 200 mA automatically associated to kV</td></tr>
<tr><td>mAs variation range @115/230Vac</td><td colspan="5">0.2 ÷ 200 mAs in 61 steps with increases of 12,5%</td></tr>
<tr><td>Range times @115/230Vac</td><td colspan="5">0.002 ÷ 2s in function of the set mAs and dose select.</td></tr>
<tr><td>kV Range</td><td colspan="5">40 ÷ 125kVp in step of 1kV</td></tr>
<tr><td>mA Range @115/230Vac</td><td colspan="5"><table>
<tr><th rowspan="2">kV</th><th colspan="4">mA</th></tr>
<tr><th colspan="2">mAs>0,63</th><th>mAs<0,63</th><th></th></tr>
<tr><th>(t<100ms) MODE1</th><th>(t>100ms) MODE 1/2</th><th>MODE 1/2</th><th></th></tr>
<tr><td>40</td><td>200</td><td>100</td><td>100</td><td></td></tr>
<tr><td>50</td><td>200</td><td>100</td><td>100</td><td></td></tr>
<tr><td>60</td><td>190</td><td>95</td><td>95</td><td></td></tr>
<tr><td>70</td><td>180</td><td>90</td><td>90</td><td></td></tr>
<tr><td>80</td><td>170</td><td>85</td><td>85</td><td></td></tr>
<tr><td>90</td><td>160</td><td>80</td><td>80</td><td></td></tr>
<tr><td>100</td><td>160</td><td>80</td><td>80</td><td></td></tr>
<tr><td>110</td><td>130</td><td>65</td><td>65</td><td></td></tr>
<tr><td>120</td><td>110</td><td>55</td><td>55</td><td></td></tr>
<tr><td>125</td><td>120</td><td>50</td><td>50</td><td></td></tr>
</table></td></tr>
<tr><td>mAs value in function of kV @115/230Vac</td><td colspan="5">0,2 ÷ 200mAs in 61 steps with increases of 12,5%<table>
<tr><th>mAs</th><th>kV</th></tr>
<tr><td>0,2 ÷ 200</td><td>40</td></tr>
<tr><td>0,2 ÷ 180</td><td>41 ÷ 45</td></tr>
<tr><td>0,2 ÷ 160</td><td>46 ÷ 52</td></tr>
<tr><td>0,2 ÷ 140</td><td>53 ÷ 62</td></tr>
<tr><td>0,2 ÷ 125</td><td>63 ÷ 72</td></tr>
<tr><td>0,2 ÷ 100</td><td>73 ÷ 92</td></tr>
<tr><td>0,2 ÷ 80</td><td>93 ÷ 112</td></tr>
<tr><td>0,2 ÷ 71</td><td>113 ÷ 125</td></tr>
</table></td></tr>
</table>

## 6.4. Environmental data

| Description | Normal use | Transport and storage |
|---|---|---|
| *Temperature* | From +10°C to +40°C | From -25°C to +70°C |
| *Relative humidity* | From 30% to 75% non condensing | From 10% to 90% non condensing |
| *Pressure* | From 700 to 1060hPa | From 500 to 1060hPa |

## 6.5. Mechanical data

| Description | Data |
|---|---|
| *Weight* | approx.185 Kg (408 Lb) |
| *Max. width* | 700mm (27,56in.) |
| *Length in transport position* | 1338mm (52,68in.) |
| *Max. height in transport position* | 1458mm (57,40in.) |
| *Max. height with the arm at the max. extension* | 2258mm (88,90in.) |
| *Control panel height* | 1000mm (39,37in.) |
| *Focus-floor distance* | 456 ÷ 2018mm (17,95 ÷ 79,45in.) |
| *Arm rotation around the vertical axis* | n.a. |
| *Monobloc rotation around the arm axis* | ±180° |
| *Monobloc rotation around its axis* | 151° (+133° ÷ -18° in respect of the vertical axis) |
| *Max. height of the front unit leg* | 105mm (4,13in.) |
| *Cassette holder* | 5 cassettes format 35 x 43cm (12x15in.) |
| *Movement* | Manual.<br>Double front swiveling wheel.<br>Parking brake<br>Handle for tilting (obstacles overcoming) |
| *Wheels diameter* | Rear:<br>wheel Ø250mm (9,84in.) width 50mm (1,97in.)<br>Front:<br>double wheel Ø 80mm (3,15in.) width 22mm (0,87in.) |

### 6.5.1. Unit sizes

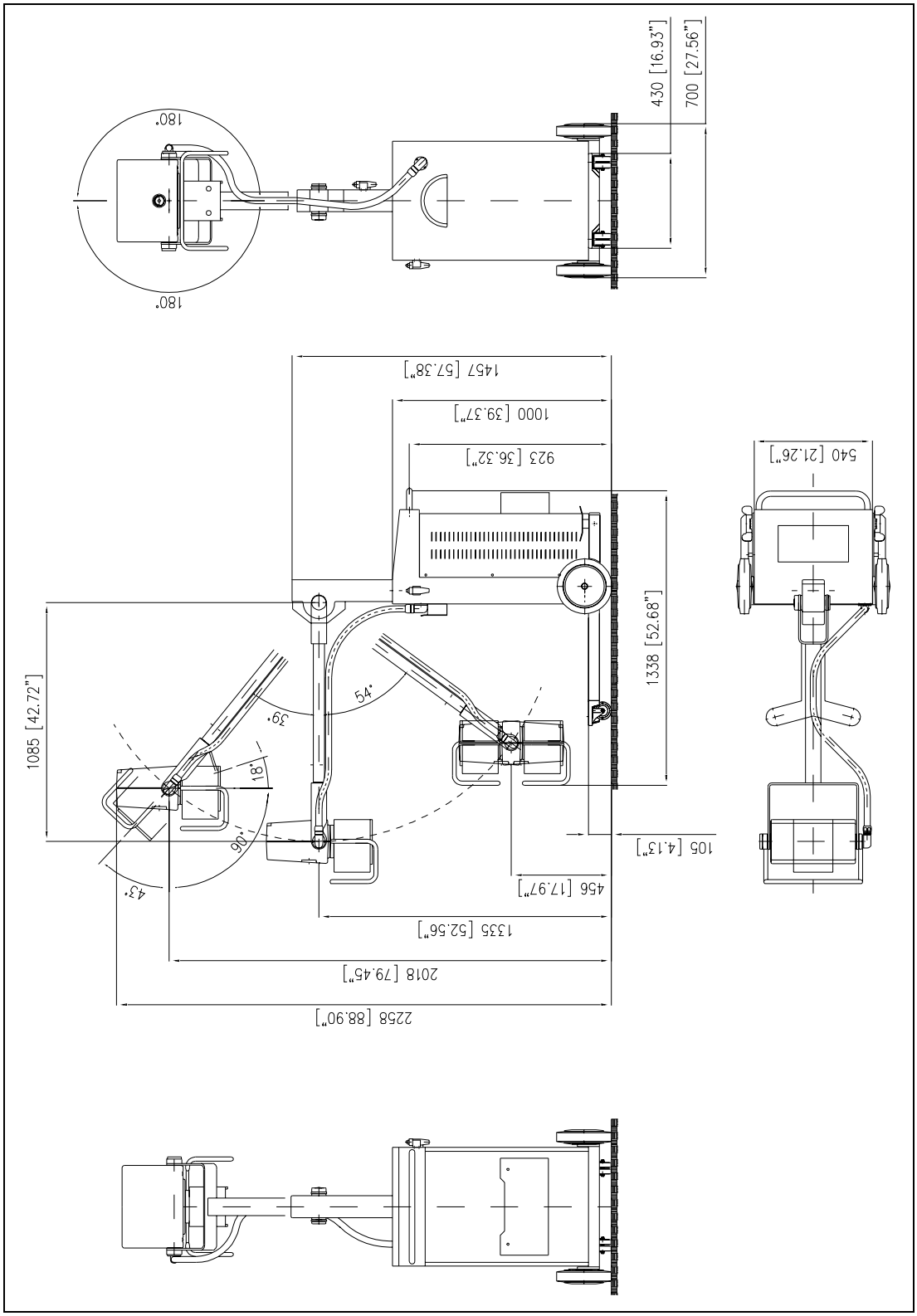



Figure 15

## 6.6. Components specifications

### 6.6.1. Generator

| Description | Data |
|---|---|
| *Inverter* | IHF 2015 |
| *Working frequency* | 20kHz max |
| *Max. inverter frquency in high voltage* | 40kHz |
| *Power supply* | 350Vdc max |
| *Dimensions* | 190x130x140 mm (7,48x5,12x5,51 in.) |
| *Max. absorbed current* | 50A |
| *Technology* | IGBT |
| *Safeties* | overcurrent<br>overvoltage<br>IGBT driver fault |
| *Generator power in constant DC current (IEC 601-1)* | 15kW<br>(150mA @ 100kV per 0.1s) |
| *Max. voltage to the tube* | 125kVp |
| *Max. ripple at 100kVp* | <2% |
| *Rise time at 100kVp* | <2 ms |
| *Max. current in radiography* | 200mA |

## 6.6.2. Tube-Housing Assembly

X-Ray Tube

| Description | Data |
|---|---|
| *Type* | X22 0.8/1.3 |
| *Nominal anode power (IEC 613, EN 60613)* | 16kW/32kW |
| *Nominal foci size (IEC 336, EN 60336)* | 0.8mm – 1.3 mm |
| *Speed of rotation* | 2850 rpm @ 50Hz |
| *Anode diameter* | 64mm (2,52in.) |
| *Anode material* | Tungsten |
| *Anode angle* | 15° |
| *Min. inherent filtration (IEC 522)* | 0.7mmAl eq. |
| *Thermal anode capacity* | 80kJ (107kHU) |
| *Max. continuous anode dissipation* | 300W |
| *Max. anode cooling speed* | 22kJ/min (29.5kHU/min) |
| *Nominal high-voltage* | 130kV |
| *Max. filament current* | 5.4A |

Tube seasoning

After a long idle period (3 months or more), it is necessary to proceed to the X-RAY TUBE SEASONING. The procedure and the tube seasoning modes are described in the Service Manual.

**Dimensions**

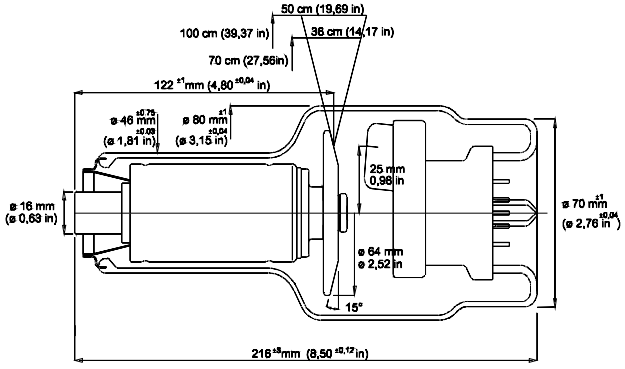



Figure 16

**Heating and cooling curves of anode**

Stored energy (kJ) / Time (min)

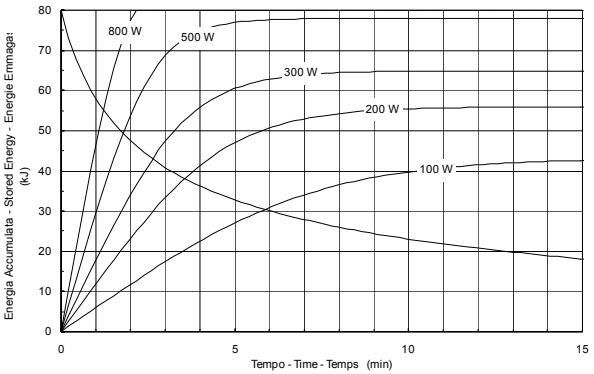



Figure 17

**Single load curves**
**0.8 - 3~ - 3000min$^{-1}$**

Anodic current (mA) / Exposure Time (s)

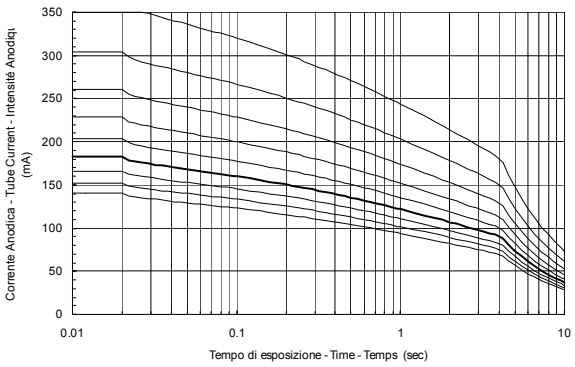



Figure 18

**Single load curves**
**1.3 - 3~ - 3000min$^{-1}$**

Anodic current (mA) / Exposure Time (s)

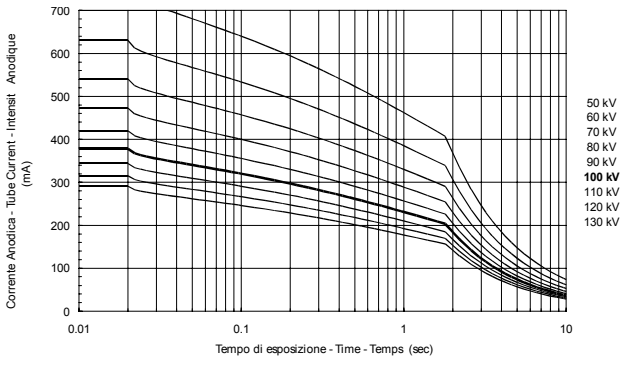



Figure 19

*Monobloc*

| Description | Data |
|---|---|
| *Monobloc* | MHF 2015 |
| *Weight* | 19 Kg (41,89Lb) |
| *Dimensions* | 320x140x255mm (12,60x5,51x10,04in.) |
| *X-ray tube* | X22 0.8/1.3 (Large focus not used) |
| *Anode* | Rotating (2850rpm at 50Hz)(3400rpm at 60Hz) |
| *External thermostat* | 57° |
| *Thermal monobloc capacity* | 600kJ (800kHU) |
| *Max continuous thermal dissipation of monobloc* | 55W |
| *Total filtration* | 2.7mm Al |
| *Leakage radiation* | <1mGy/h according to IEC 601-1-3 |
| *Loading, heating and cooling curves* | See the enclosed diagrams |
| *H.V. transformer insulation* | Oil bath |

Dimensions

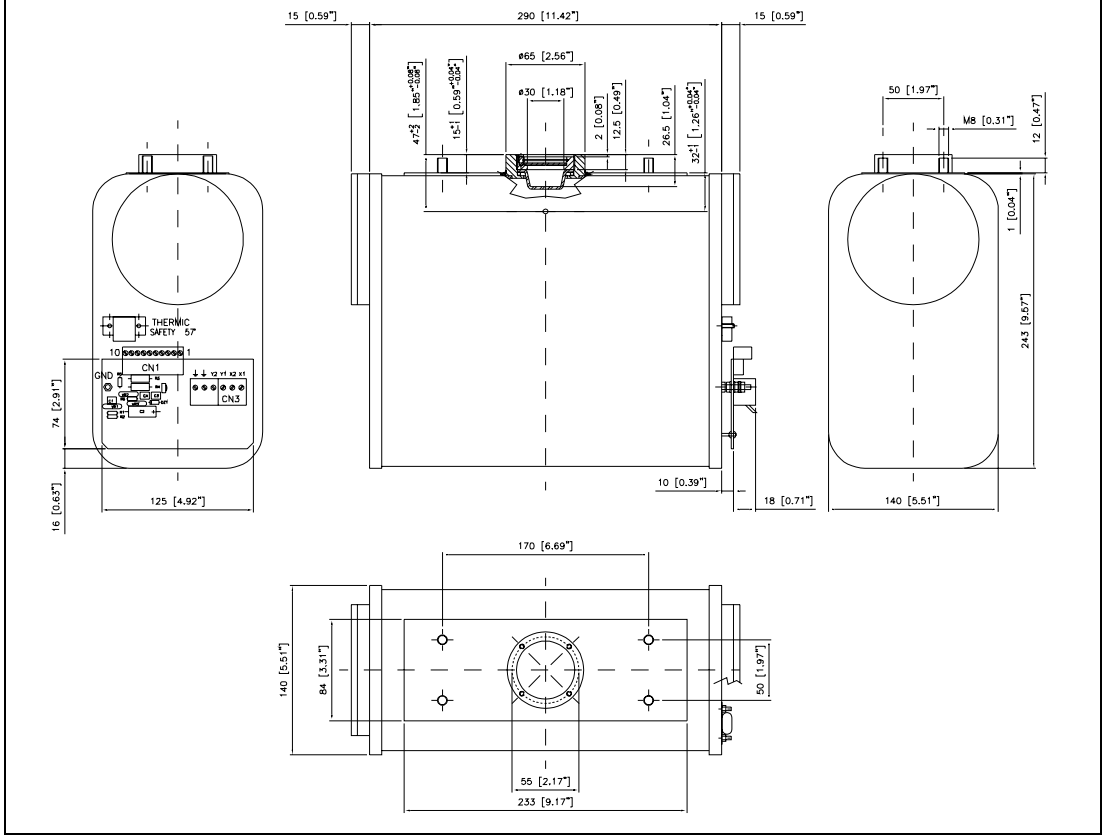



Figure 20

Heating and cooling curves of monobloc

Stored energy (kJ) / Time (min)

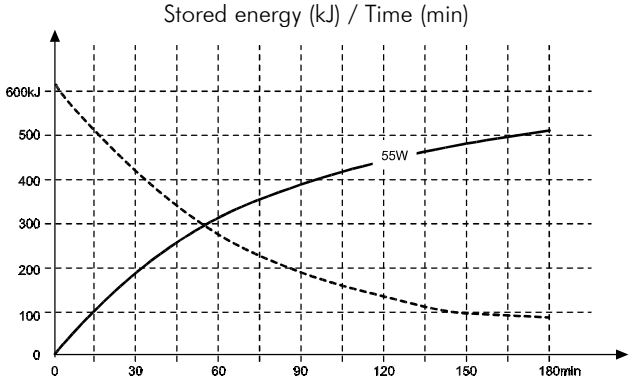



Figure 21

### 6.6.3. Collimator

| Description | Data |
|---|---|
| *Type, brand and model* | Manual with internal light source (Ralco R221) |
| *Collimator* | Square field, multilayers |
| *Light source* | Halogen Lamp 12V 100W with timed switching-on at approx. 30s |
| *X-ray field* | 43x43cm (16,93x16,93in.) at 1m (39,37in.) DFF |
| *Luminous intensity* | 160lux at 1m (39,37in.) DFF |
| *Contrast ratio* | 4:1 |
| *Measurement of focus-film distance* | Extractable meter |
| *Rotation* | ±115° |
| *Weight* | 8,4kg (18,52Lb) |
| *Sizes* | 183x168x256mm (7,20x6,61x10,08in.) |
| *Accessories* | Prearrangement to insert the dosimeter |
| *Max protection against leaked radiation (EN60601-1-3 par.29.204.3)* | 125kV 4mA |
| *Indicator accuracy (EN60601-1-3 par.29.202.8)* | It corresponds to the x-ray fields with tolerance lower than 2% of used FFD |
| *Inherent filtration (EN60601-1-3 par.29.201.2/29.201.6)* | 2.0mmAl eq. |
| *Light field accuracy (EN60601-1-3 par.29.202.9)* | It corresponds to the x-ray fields with tolerance lower than 2% of the used FFD. |
| *Classification EN60601-1 par.5*<br>*Protection against electrical hazards*<br>*Protection against direct and indirect contacts*<br>*Protection against water penetration* | <br>Class I<br>Unit with applied part Type B<br>Common protection (IPXO) |

### 6.6.4. DAP meter (dose-area product meter) (optional)

This device is installed only on request.

| Description | Data |
|---|---|
| *Type, brand and model* | Dosimeter with ionization chamber, PTW-Freiburg DIAMENTOR PX - T11020-00011 |
| *Measurement unit* | $cGycm^2$ |
| *Resolution* | $0.1cGycm^2$ |
| *Dose-area product range* | $0.3 \div 15000\ cGycm^2$ |
| *Dose-area product summation range* | $00000.0 \div 99999.9cGycm^2$ |
| *Max. measuring range* | 118mm x 118mm (4,65x4,65in.) |

## *6.7. Accessories and options*

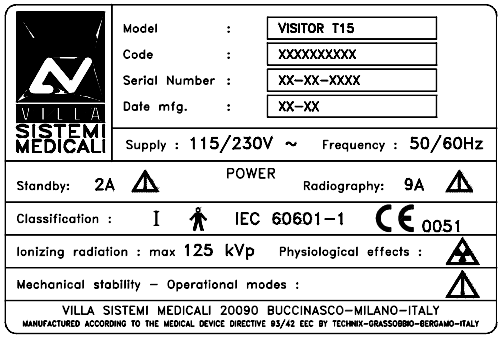
| Description | |
|---|---|
| *X-ray handswitch with extendible cable* | Standard |
| *Ionization chamber dosimeter, mod. DIAMENTOR PX* | Optional |

## *6.8. Compliance with Directives and Technical Standards*

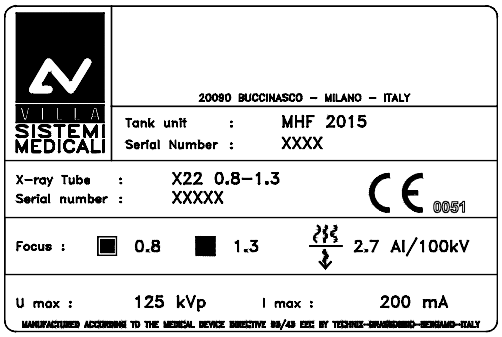
| Reference | Description |
|---|---|
| *MDD 93/42/EEC* | Medical Devices Directive (CE mark) |
| *IEC 60601-1* | Medical devices safety |
| *IEC 60601-1-2* | Electromagnetic compatibility |
| *IEC 60601-1-3* | Protection against ionizing radiation |
| *IEC 60601-2-7 2nd edition* | High voltage generators |
| *IEC 60601-2-28* | Tube – housing groups |
| *IEC 60336* | X-ray tubes focus |

## 6.9. *Labels and symbols*

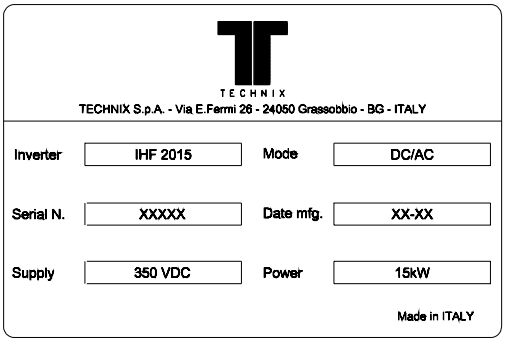
### 6.9.1. Labels of the unit



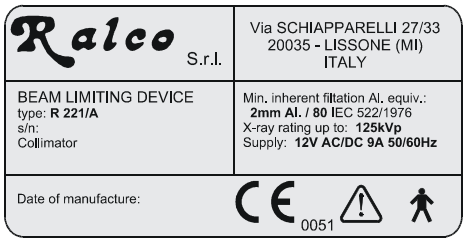

unit label


VILLA SISTEMI MEDICALI
20090 BUCCINASCO – MILANO – ITALY
Tank unit : MHF 2015
Serial Number : XXXX
X–ray Tube : X22 0.8–1.3
Serial number : XXXXX
0051
Focus : 0.8 1.3
2.7 Al/100kV
U max : 125 kVp
I max : 200 mA

external monobloc label



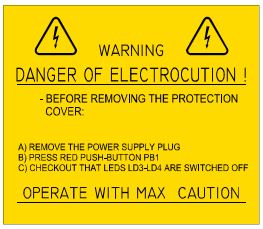

inverter label




collimator label

Figure 22

### 6.9.2. Internal symbols

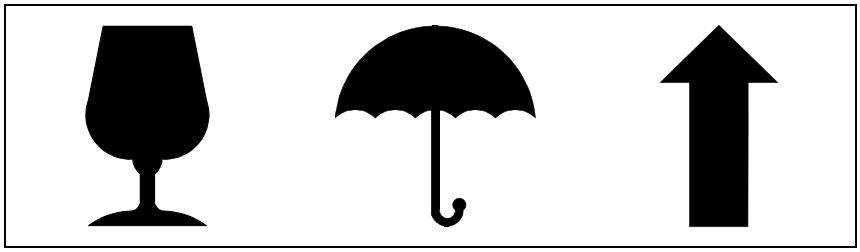
| | |
|---|---|
| | Protective ground clamp |
| | Dangerous voltage |
|  WARNING<br>DANGER OF ELECTROCUTION !<br>- BEFORE REMOVING THE PROTECTION COVER:<br>A) REMOVE THE POWER SUPPLY PLUG<br>B) PRESS RED PUSH-BUTTON PB1<br>C) CHECKOUT THAT LEDS LD3-LD4 ARE SWITCHED OFF<br>OPERATE WITH MAX CAUTION | Precautionary warning |

### 6.9.3. Various symbols

| | | | |
|---|---|---|---|
| | Unit OFF | | Unit Type B |
| | Unit ON | | Total filtration |
| | Ionizing radiation | | Alternate voltage |
| | Large focus | | Equipotential node |
| | Small focus | | |

### 6.9.4. Packing label

It is stuck outside the packing with red writings on white background.



Fragile | Protect from rain | Upper edge of the packing

# DOCUMENT STATUS

| *Rev.* | *Date* | *Pages* | *Modification description* |
|---|---|---|---|
| 0 | 26.08.03 | - | Document approval |
| 1 | 14.01.04 | all | Documents general revision. |
| 2 | 26.03.04 | 17 | Performed modification of the APR values in the unit software. |
| 3 | | | |
| 4 | | | |
| 5 | | | |